Fimoxyclav®

Amoxycillin Trihydrate BP / Amoxycillin Sodium BP
Clavulanate Potassium USP

50120

Presentation
Fimoxyclav 375 tablet: White to off white, circular, bevelled, biconvex film coated tablet. Both faces are plain; each tablet contains Amoxvcillin Trihydrate BP equivalent to Amoxycillin 250mg and Clavulanate Potassium UP equivalent to Clavulanic Acid 125mg.
Fimoxyclav 625 tablet: White to almost white, capsule-shaped bi-convex film coated tablet. Both faces are plain; each tablet contains Amoxycillin Trihydrate BP equivalent to Amoxycillin 500mg and Clavulanate Potassium UP equivalent to Clavulanic Acid 125mg.
Fimoxyclav 1g tablet: Each tablet contains Amoxycillin Trihydrate BP equivalent to Amoxycillin 875mg and Clavulanate Potassium UP equivalent to Clavulanic Acid 125mg. The ratio of Amoxycillin: Clavulanic Acid is 7:1.
Fimoxyclav suspension: Bottle containing powder for preparation of 100ml suspension; when reconstituted each 5ml contains Amoxycillin Trihydrate BP equivalent to Amoxycillin 125mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 31.25mg.
Fimoxyclav bid suspension: Bottle containing powder for preparation of 50ml suspension; when reconstituted each 5ml contains Amoxycillin Trihydrate BP equivalent to Amoxycillin 400mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 57mg. The ratio of Amoxycillin: Clavulanic Acid is 7:1.
Fimoxyclav ES suspension:
Is an off-white powder, which, when reconstituted, yields an off-white to tan colored, banana flavored suspension. When reconstituted each 5 mL contains 600 mg amoxicillin (as amoxicillin trihydrate) and 42.9 mg clavulanic acid (as potassium clavulanate), a 14:1 ratio.
Fimoxyclav 0.6 IV injection: Sterile powder in vials providing Amoxycillin Sodium BP equivalent to Amoxycillin 500mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 100mg.
Fimoxyclav 1.2 IV injection: Sterile powder in vials providing Amoxycillin Sodium BP equivalent to Amoxycillin 1000mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 200mg.

Uses
Fimoxyclav (Clavulanate-potentiated Amoxycillin) is a broad spectrum bactericidal antibiotic effective against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxycillin to embrace a wider range of organisms, including many resistant ones to other beta-lactam antibiotics. Fimoxvclav is indicated for the treatment of bacterial infections at the following sites :
Upper respiratory tract infections including ENT infections: Tonsillitis, recurrent tonsillitis, peritonsillar abscess, sinusitis, pharyngitis, laryngitis, laryngo-tracheitis, otitis media.
Lower respiratory tract infections: Acute and chronic bronchitis, lobar and bronchopneumonia, aspiration pneumonia, lung abscess, empyema.
Urinary tract infections: Cystitis, urethritis, epididymitis, pyelonephritis.
Obstetric and gynecological infections: Bacteriuria in pregnancy, septic abortion intra-abdominal sepsis, puerperal sepsis.
Skin and soft tissue infections: Cellulitis. infected wounds, infected burns, abscesses, carbuncles, furunculosis, impetigo.
Bone and joint infections: Osteomyelitis, septic arthritis.
Other infections: Septicaemia, bacterial endocarditis, cerebral abscess, major head and neck surgery, peritonitis, cholecystitis. cholangitis, dental abscess.
Fimoxyclav is also of value for the prophylaxis of post-operative infections, in patients undergoing surgical procedures associated with a high risk of infection.
Bites of animals and man.
Persistent & recurrent Otitis Media typically caused by Streptococcus pneumoniae, Haemophiles influenzae and Moraxella catarrhalis.

Dosage and administration
Adults:
Oral: For adults and children over 12 vears: The usual dose is one Fimoxvclav 375 tablet every 8 hours. for severe infections one Fimoxvclav 625 tablet ever 8 hours Dosage in dental infections (e.g. dentoalveolar abscess or odontogenic infections) One Fimoxyclav 375 tablet every 8 hours for five days or as advised by the physician The duration of therapy varies according to the course of the diseases. As with antibiotic therapy in general practice, administration of Fimoxyclav should be continued for a minimum of 48-72 hours after the patient has become febrile or evidence of bacterial eradication has been obtained.
Parenteral: Usually 1.2g IV eight hourly. In more serious infections, increase frequency to six-hourly intervals.
Adult dosage for surgical prophylaxis: The usual dose is 1.2g Fimoxyclav intravenous given at the induction of anaesthesia. Operations where there is a high risk of infection, e.g. colorectal surgery, may require three, and up to four, doses of 1.2 g Fimoxyclav intravenous in a 24-hour period. These doses are usually given at 0, 8, 16 (and 24) hours. This regimen can be continued for several days if the procedure has a significantly increased risk of infection.
Clear clinical signs of infection at operation will require a normal course of intravenous or oral Fimoxyclav therapy post-operatively.
Administration: Fimoxyclav intravenous may be administered either by intravenous injection or by intermittent infusion. It is not suitable for intramuscular administration. 600 mg vial: To reconstitute dissolve in 10 ml Water for Injection BP. (Final volume 10.5ml.)
1.2 g vial: To reconstitute dissolve in 20 ml Water for Injections BP. (Final volume 20.9 ml.) Fimoxyclav Intravenous should be given by slow intravenous injection over a period of 3-4 minutes and used within 20 minutes of reconstitution. Do not freeze. It may be injected directly into a vein or via a drip tube.
Alternativelv, Fimoxvclav intravenous may be infused in Water for Injection BP or Sodium Chloride Intravenous Injection BP (0.9% w/V). Add without delay, 600 mg-reconstituted solution to 50-ml infusion fluid or 1.2 g reconstituted solution to 100 ml infusion fluid (e.g. using a minibag or in-line burette). Infuse over 30-40 minutes and complete within 4 hours of reconstitution. Any residual antibiotic solutions should be discarded.
Fimoxyclav intravenous is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solution should, therefore. not be added to such infusions but may be injected into the drip tubing over a period 3-4 minutes. Fimoxyclav intravenous should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.
Children:
Oral: For children upto 12 years: For otitis media, sinusitis and lower respiratory tract infections, the dose should be 40mg/kg/day based on the amoxycillin component in divided doses every 8 hours. Children below 12 years should not take tablet. For Children over 6 to 12 years: 2 teaspoonful of Fimoxyclav suspension every 8 hours.
Children 1 to 6 years: 1 teaspoonful of Fimoxyclav suspension every 8 hours. Children below 1 year: 25mg/ kg/ day in divided doses every 8 hours, for example, a 7.5kg child would require 2.5ml suspension t.i.d. Dose may be doubled in severe infections.
Treatment should not be extended beyond 14 days without review. Fimoxyclav may be taken on a full or empty stomach.
To reconstitute 100 ml suspension: Add 85 ml (17 x 5 ml spoonful) boiled and cooled water to the bottle. Shake well until all powder dispersed.
Parenteral: Children 3 months-12 years: Usually 30mg/kg Fimoxyclav eight hourly. In more serious infections, increase frequency to six-hourly intervals.
Children 0-3 months: 30 mg/kg Fimoxyclav every 12 hours in premature infants and in full term infants during the perinatal period, increasing to eight hours thereafter.
*Each 30mg Fimoxyclav provides co-amoxiclav 25/5.
Administration in renal failure: The dose should be adjusted in case of patients with renal impairment.
Adults: Mild impairment (Creatinine clearance> 30ml/min: No change in dosage.
Moderate impairment (Creatinine clearance 10-30 ml/min) : One or two Fimoxyclav 375 tablet 12 hourly or 1.2 g IV followed by 600 mg IV 12 hourly.
Severe impairment (Creatinine clearance <10 ml/min): Not more than one Fimoxvclav 375 tablet 12 hourly or 1.2 g IV followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of Fimoxyclav and an additional 600mg IV does may need to be given during dialysis and at the end of dialysis.
Children : Similar reductions in dosage should be made for children.
Administration in hepatic impairment : Dose with caution; monitor hepatic function at regular intervals.

Dosage and administration for Fimoxyclav 1g tablet and Fimoxyclav bid suspension:
To reconstitute 50ml bid suspension: Add 43ml (8x 5ml spoonfuls) boiled and cooled water to the bottle. Shake well until all powder is dispersed.
The exact dose for children (aged over 3 months) is established according to their body weight. Depending on the severity of the infection, the usual dosage in children weighing less than 40kg is 25-45mg/kg daily (based on the Amoxycillin content), divided in two equal portions.
Children weighing less than 40kg should not be given tablets.

Dosage recommendations for every 12 hours administration of 457mg/5ml suspension in children

Infection	Daily dose (based on the Amoxycillin content)
Otitis, sinusitis, lower respiratory tract infections and severe infections	45 mg/kg/day
Mild to moderate infections	25 mg/kg/day

A calibrated dropper is supplied to facilitate dosing of the 457mg/ml suspension (1 dropper = 5ml, 1/4 dropper = 1.25ml, 1/2 dropper = 2.5ml, 3/4 dropper = 3.75ml).
The usual daily dose for severe infections or respiratory trac infections is 1 tablet of 1000ng every 12 hours.

The maximum daily dose of clavulanic acid (as the potassium salt) is 600mg for adults and 10mg/kg body weight for children.
The maximum daily dose of Amoxycillin is 6g for adults and 45mg/kg body weight for children.In the presence of severe renal failure (creatinine clearance 10-30ml/min). the dosage should be reduced or the dosing intervals increased, in anuric patients even to 48 hours or mine.
The recommended dose for Fimoxyclav ES is 90/6.4 mg/kg/day in 2 divided doses at 12-hourly intervals for 10 days (see chart below). There is no experience in pediatric patients weighing > 40 kg, or in adults. There are no clinical data on Fimoxyclav ES in children under 3 months of age.

Body weight (kg)	Volume providing 90mg/kg/day
8	3.0 mL twice daily
12	4.5 mL twice daily
16	6.0 mL twice daily
20	7.5 mL twice daily
24	9.0 mL twice daily
28	10.5 mL twice daily
32	12.0 mL twice daily
36	13.5 mL twice daily

Fimoxyclav ES does not contain the same amount of clavulanate (as the potassium salt) as any of the other Fimoxyclav suspensions. Other Fimoxyclav suspensions should not be substituted for Fimoxyclav ES, as they are not interchangeable.

Pharmacological properties
Resistance to many antibiotics is caused by bacterial enzymes, which destroy the antibiotic before it can act on the pathogen. The clavulanate in Fimoxyclav anticipates this defence mechanism by blocking the beta-lactamase enzymes, thus rendering the organisms sensitive to Amoxycillin's rapid bactericidal effect at concentrations readily attainable in the body.
Clavulanic acid acts as a "suicidal" molecule and irreversiblv binds to bacterial betalactamases. Clavulanate in association with amoxycillin acts as an antibiotic with wide application in hospital and general practice. Fimoxyclav is bactericidal to a wide range of organisms including :
Gram-positive aerobes: Enterococcus faecalis Enterococcus faecium* Streptococcus pneumonia, Streptococcus pyogenes, Streptococcus viridans, Staphylococcus aureus* Coagulase negative staphylococci* (including Staphylococcus epidermidis *)*
Corynebacterium species, Bacillus anthracis Listeria monocytogenes.*
Gram-positive anaerobes: Clostridium species, Peptococcus species, Peptostreptococcus
Gram-negative aerobes: Haemophilus influenza Moraxella catarrhalis* (Branhamella catarhalis), Escherichia coli*, Proteus mirabilis*, Proteus vulgaris*, Klebsiella species*. Salmonella species*, Shigella species*, Bordetella pertussis, Brucella species, Neisseria gonorrhoeae*, Neisseria meningitidis*, Vibrio cholerae, Pasteurella multocida.*
Gram-negative anaerobes: Bacteroides species including B. fragilis.*
*Some members of these species of bacteria produces beta-lactamase, rendering them insensitive to amoxycillin alone).
Pharmacokinetic properties : The pharmacokinetics of the two components of Fimoxyclav are closely matched. Both clavulanate and amoxvcillin have low levels of serum protein binding; about 70% remains free in the serum. Doubling the dosage of Fimoxyclav approximately doubles the serum levels achieved.

Contra-indications, warnings, etc.
Penicillin hypersensitivity. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. cephalosporins. Infectious mononucleosis, lymphocytic leukemia.
Patients taking penicillin beforehand may lead to serious / occasional anaphylactic reaction. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen therapy, IV steroid, Airway management including intubation should be administered as indicated.

Precautions
Changes in liver function tests have been observed in some patients receiving co-amoxiclav. The clinical significance of these changes is uncertain but co-amoxiclav should be used with caution in patients with evidence of hepatic dysfunction. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported very rarely. Prolonged use may also occasionally result in overgrowth of non- susceptible organisms. During the administration of high doseg of co-amoxiclav adequate fluid intake and urinarv output should be maintained to minimize the possibility of side effects.
Pregnancy and lactation: There is no evidence of harm to the fetus due to co-amoxiclav. In the FDA Pregnancy Categories, Amoxycillin/clavulanic acid has been assigned a B rating. Animal studies with orally and parenterally administered co-amoxyclav have shown no teratogenic effect. The drug has been used orally in human pregnancy in limited number of cases with no untoward effect. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician. Co-amoxiclav may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.
Possibility of super infection with mycotic / bacterial pathogens should be monitored if pseudomonas/ candida is involved, the drug should be discontinued and appropriate therapy is instituted.

Drug interactions
Prolongation of bleeding time and prothrombin time have been reported in some patients receiving co-amoxyclav. Co-amoxyclav should be used with care in patients on anti-coagulation therapy. Incommon with other broad-spectrum antibiotics, co-amoxyclav may reduce the efficacy of oral contraceptives and patients should be warned accordingly. Probenecid decreases the renal tubular secretion of amoxycillin Concomitant use with co-amoxyclav may result in increased and prolonged blood levels of amoxvcillin but not of clavulanic acid. In combination with allopurinol, the incidence of exanthema is more frequent. Co-amoxyclav is physically and chemically incompatible with aminoglycosides. In individual cases the drug can cause prolongation of prothrombin time, therefore care is needed before starting. concurrent treatment with oral anticoagulants. Equally, concomitant use of disulfiram
should be avoided.

Side-effects
Side effects as with amoxycillin, are uncommon and mainly of a mild and transitory nature. Diarrhoea, indigestion, nausea, vomiting and candidiasis have been reported Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) has been reported rarely. Nausea although uncommon, is more often associated with higher oral dosages. If gastro-intestinal side effects occur with oral therapy, they may be reduced by taking Fimoxyclav at the start of meals. Hepatitis and cholestatic jaundice have been reported rarely but are usually reversible. Urticarial and ervthematous rashes sometimes occur. Rarely erythema multitorme, Stevens-Johnson Syndrome and exfoliative dermatitis have been reported. In common with other beta-lactam antibiotics, angioedema and anaphylaxis may be reported rarely. Pseudomembranous colitis has been reported with nearly all antibacterial agents and has ranged from mild to life threatening.

Overdosage
Problems of overdose with co-amoxyclav are not likely to occur; if encountered, may be treated symptomatically. It may be removed from the circulation by haemodialysis.
Patients who has experienced GIT symptoms including stomach, abdominal pain, vomiting and diarrhea. Rash, hypersensitivity and drowsiness has also been observed in small number of patients.

Pharmaceutical precautions
After reconstitution, suspension should be stored in a refrigerator or within 20.8°C and used within 7 days. Reconstituted injection should be used within 20 minutes of reconstitution. Do not freeze.

Storage conditions
Fimoxyclav preparations should be stored in dry place. Tablets, dry powder and injection should be kept at 25° C or below. Reconstituted suspension should be stored in refrigerator and used within 7 davs.
SHAKE THE BOTTLE WELL BEFORE TAKING EACH DOSE.

Package quantities
Fimoxyclav 375 tablet: Box of 5x6 tablets in alu-alu blisters.
Fimoxvclav 625 tablet: Box of 5x6 tablets in alu-alu blisters.
Fimoxyclav 1g tablet: Box of 4 x6 tablets in alu-alu blisters.
Fimoxyclav suspension: Bottle containing powder to produce 100ml of suspension (125mg/31.25mg/5ml) when reconstituted.
Fimoxyclav bid suspension: Each bottle contains powder to produce 50ml suspension (400mg/57mg/5ml).
Fimoxyclav ES: Each bottle contains powder to produce 75ml suspension (600mg/42.9mg/5ml)
Fimoxyclav 0.6 IV injection: Box of one combipak. Each combipack contains: 1 vial of Amoxvcillin Sodium P equivalent to Amoxycillin 500mg + Clavulanate Potassium USP equivalent to Clavulanic acid 100 mg, 1 ampoule of 10ml of Water for Injection BP for dilution and a sterile disposable syringe.
Fimoxyclav 1.2 IV injection: Box of one combipack. Each combipack contains: 1 vial of Amoxycillin Sodium BP equivalent to Amoxycillin 1g + Clavulanate potassium USP equivalent to Clavulanic acid 200 mg, 1 ampoule of 20ml of Water for Injection BP for dilution and a sterile disposable syringe.

Do not use later than the date of expiry.
Keep all medicines out of the reach of children.
To be dispensed only on the prescription of a registered physician.

Manufactured by:
synovia
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Direction Slip Artwork Legend

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